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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,748	11/19/1999	WALTER DIEMBECK	BEIERSDORF56	4709

7590

12/31/2002

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EXAMINER

LAMM, MARINA

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/367,748

Applicant(s)

DIEMBECK ET AL.

Examiner

Marina Lamm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 18-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the amendment filed 9/30/02. Claims pending are 1-15 and 18-27. Claim 16 has been cancelled.

Claim Rejections - 35 USC § 112

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of Claims 1, 2, 4-8 and 11-15 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of rosacea and coperose, does not reasonably provide enablement for the prophylaxis of these conditions, is maintained for the reasons of the record. New Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of rosacea and coperose, does not reasonably provide enablement for the prophylaxis of these conditions, for the reasons of the record.

Claim Objections

3. Claims 3, 9, 10 and 19-21 are objected to because of the following informalities: the use of abbreviations. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The rejection of Claims 1-4, 7, 8, 11, 14, 15 and 18 under 35 U.S.C. 102(b) as being anticipated by Giacomoni is maintained for the reasons of the record.

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6. Claims 3, 9, 10 and 19-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Breton et al. (US 5,795,574).

Breton et al. teach topical compositions containing 0.0001-20% of NO-synthase inhibitors such as 7-nitroindazole, N(5)-(1-iminoethyl)-L-ornithine, methyl ester of N-nitro-L-arginine and others which can be used alone or as a mixture. See col. 1, lines 31-56; col. 15, lines 6-11, 41; Claims 25, 27, 44. The compositions of Breton et al. are used for treating certain diseases of the skin, such as rosacea. See col. 16, line 11.

Thus, Breton et al. teach each and every limitation of Claims 3, 9, 10 and 19-27.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. The rejection of Claims 5, 6, 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Giacomoni in view of either Breton et al. or Ptchelintsev et al. is maintained for the reasons of the record.

Response to Arguments

9. Applicant's arguments filed 9/30/02 have been fully considered but they are not persuasive.

With respect to the enablement rejection, the Applicant states that "Claims 1, 2, 4-8 and 11-15 were rejected by the examiner as being non-enabling for the treatment of rosacea and coperoose." See p. 4. In response, it is noted that the enablement rejection applies only to the prophylaxis of these conditions. Further, the Applicant argues that "there does not appear to a basis (sic!) for a requirement for a submission of "evidence". In response, the Applicant is

referred to MPEP 2164.05 which states that “[o]nce the examiner has weighted all the evidence and established a reasonable basis to question the enablement provided for the claimed invention, the burden falls on applicant to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would be able to make and use the claimed invention using the application as a guide. *In re Brandstadter*, 484 F.2d 1395, 1406-07, 179 USPQ 286, 294 (CCPA 1973). The evidence provided by applicant need not be conclusive but merely convincing to one skilled in the art.” (emphasis in original). Therefore, MPEP explicitly requires the Applicant to submit “persuasive arguments, supported by suitable proofs”. Further, the Applicant argues that “only three of the eight undue experimentation factors have been addressed” in the rejection. In response, according to MPEP 2164.04, “it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.” (emphasis in original). As discussed previously, the burden of enabling the prophylaxis or prevention of a disease (i.e. the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such diseases and the difficulty of proof that the administration of the drug was the agent that acted to prevent the condition. Further, the specification does not provide guidance as to how one skilled in the art would go about screening those patients susceptible to rosacea and couperose. Nor is guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed compounds in

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preventing these disease states. Accordingly, it is the Examiner's opinion that undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention.

With respect to the 102 rejection over the Giacomoni reference, the Applicant argues that Giacomoni fails to anticipate the instant claims, it is noted that Giacomoni explicitly teaches treating rosaceous acne with compositions containing a NO-synthase inhibitor in combination with a retinoid. Further, the effective amount of NO-synthase inhibitors in the compositions of Giacomoni overlaps with that of the instant invention. See Claim 2 of the translation and p. 7 of the instant specification.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541.

The examiner can normally be reached on Monday to Friday from 9 to 5.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

ml
12/29/02

JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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